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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,272	02/06/2002	H. Andrew Strong	273012012500	1974

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,272	STRONG ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2005 has been entered.

Claims 1-2, 5-19 are pending.

Any rejection that is not addresdsd in this Office Action is considered withdrawn in view of the Amended claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5-12, 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by TAP Report 1, ("Photodynamic Therapy of Subfoveal Choroidal Neovascularization in Age-related Macular Degeneration with Verteporfin." Arch Ophtalmol.1999; 117:1329-1345) (the TAP Report).

The instant claims are directed to methods of treating an ocuult choroidal neovascular (CNV) lesion comprising administering photodynamic therapy to a subject having Occult CNV, wherein the subject is assessed as having either or both (a) a small

lesion with a size less than about 4-5 disc areas or (b) poor visual acuity of less than about 65 letters prior to treatment.

The TAP Report teaches the instantly claimed method. Tap Report teaches methods of administering verteporfin, a green porphyrin (which is also known as BPD-MA, see Reg Number 129497-78-5) to patients suffering from Occult CNV. (see page 1330 under the heading *Patient Selection*, last para.). Out of the 402 Patients in the Vertoporfin arm of the study, at least 305 patients had evidence of Occult CNV(see Table 2 at page 1334, last criteria under the category *Evidence of Occult CNV*). Further, out of the same 402 patients at least 199 patients had a visual acuity of less than 53 letters (see Table 2, Vertoporfin Arm, under the category *Visual Acuity* criteria). Thus, at least about 100 patients who had received a photodynamic regimen of Verteporfin, had evidence of Occult CNV with visual acuity of less than 65.

Examiner also states that among the population in the Verteporfin Arm, 259 appear to have lesion size of less than 6 disc areas (see page 1335, table 2, under Vertoporfin Arm, Under *the Area of Lesion, MPS Disc Areas* criteria). Therefore, the population who showed Occult CNV in the TAP Report and further received verteporfin, are the same as the instantly claimed population. Said population received Verteprofin solution in amount of about 6 mg/m 2 (see abstract, also page 1332, at 1st col). Fifteen minutes after administration of the Verteprofin the CNV lesions were irradiated with a laser light for about 83 seconds in a light exposure of 50 J/CM2. (see col 1 page 1332). Accordingly, the limitations of claims 14-18 are met.

All method steps of the instantly claimed process are described for the population who showed Occult CNV prior to the therapy in the TAP Report Verteporfin Arm. Accordingly, the instantly claimed intended purpose is inherently achieved in the said population.

Applicant is also informed that the recitation of 45% efficacy of therapy in Occult CNV group, as recited in page 1338 is not a teaching away, because such conclusion does not mean that no patient has benefited from the methodology described in Vertopoifin Arm of the TAP Report. Rather, such percentage is only viewed as a comparison to the control group. Therefore, Examiner takes the position that at least a portion of the population who received the therapy and showed Occult CNV with poor visual acuity below 53 letters, fall within the scope of the instant claims and thus anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-2, 5-19 rejected under 35 U.S.C. 103(a) as being unpatentable over TAP Report in view of Zeimer US Patent 5,935,942.

The teachings of TAP report are described above. TAP report only fails to specifically describe attachment the use of a targeting ligand and the dosing of its photosensitizer per body weight of subjects.

Zeimer is used to describe the same process as in TAP report except that the photosensitzer is encapsulated or coupled with a targeting or tissue specific agent (see col 12, lines 28-50; col 14, lines 15-col 24). The process of Zeimer employs targeted liposomes (col 25-26) for patients having Occult CNV.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a targeting agent, such as an antibody, to the photosensitizer employed in TAP report, because as suggested by Zeimer, the ordinary skill in the art would have had a reasonable expectation of success in improving the clinical outcome

of such photodynamic therapy. Further, absent a showing of criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the dosing ranges of the photosensitizer in TAP report by routine experimentation and express it based on the body weight of subjects.

Conclusion

4. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER